What's new on PrEP?

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No financial conflicts of interest to declare

Overview of presentation

- Event-driven PrEP
- Other PrEP products in pipeline
- Adjusting PrEP services in context of COVID-19

211

211

event-driven PrEP

event-based PrEP

on-demand

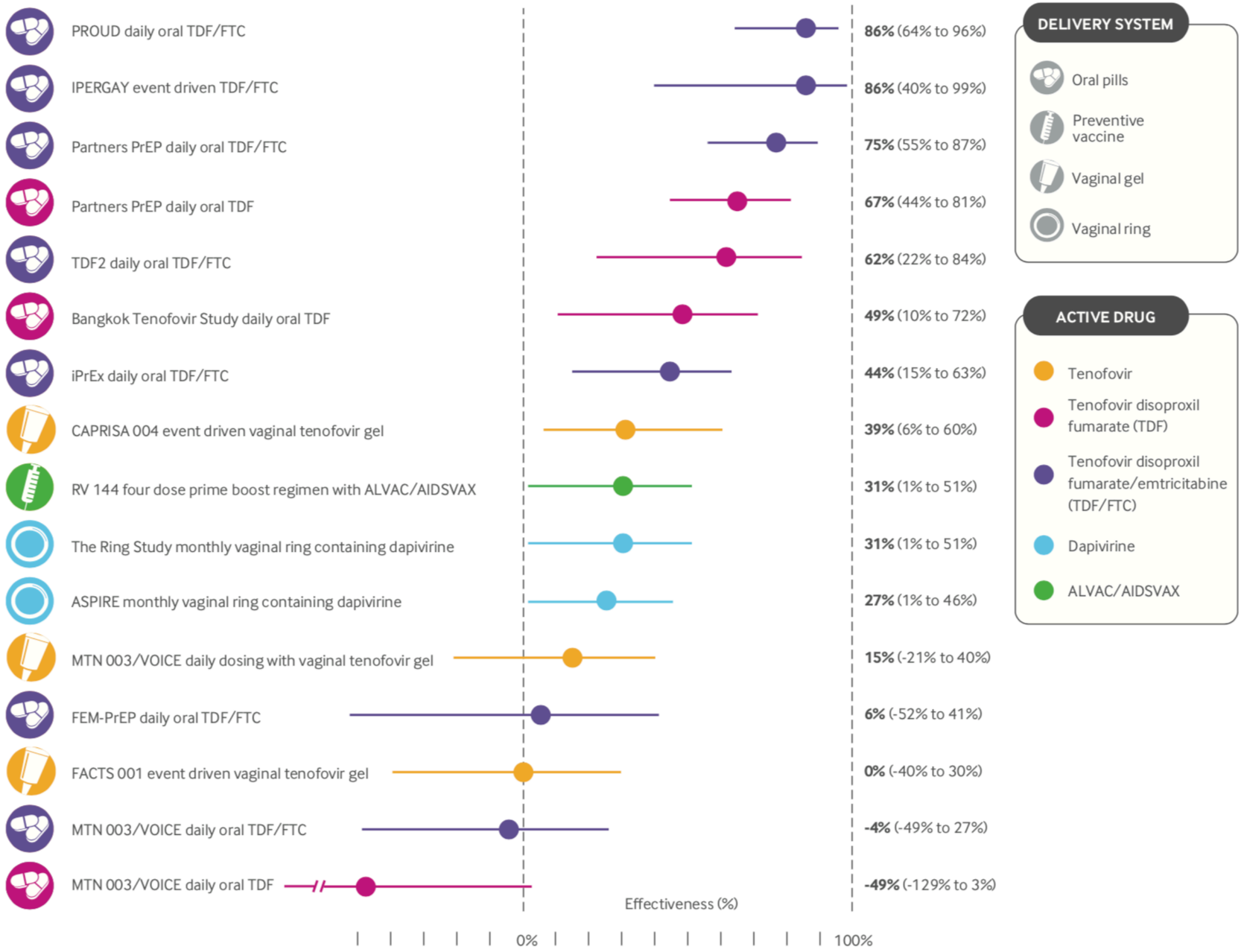
211

event-driven PrEP

event-based PrEP

on-demand

Extensive PrEP clinical research has shown that PrEP is super effective in HIV prevention (different modalities)



Desai et al, BMJ 2017

How does it work?

1 pill every day / 7 days before sex

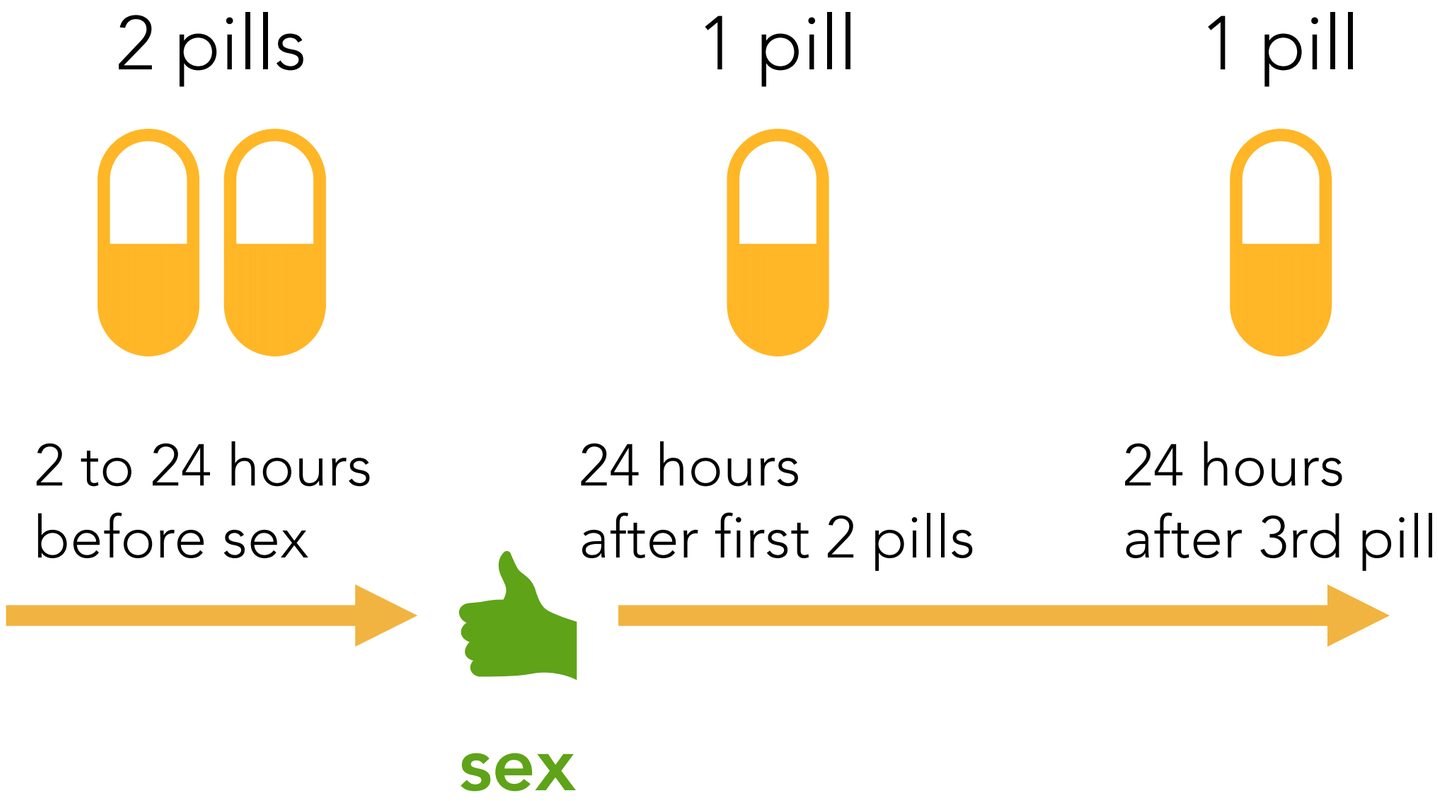
7 days

sex (period of risk)

Keep taking 1 pill every day after last sexual encounter

7 days

MSM can take PrEP ‘on-demand’



https://www.who.int/hiv/pub/prep/211/en/

ED-PrEP is NOT recommended in the following circumstances:

- Chronic hepB infection 
- cis-women 
- Transgender persons (evidence suggests hormones may reduce levels of tenofovir) 

Critical evidence that ED-PrEP is highly effective for cis-MSM

- IPERGAY (France, Canada) (n= 400): PrEP dosing 2+1+1 (first dose 2-24h before sex; second dose 24h after the first one; third dose 48h after the first one)
  - **86% reduction** in HIV risk in the placebo controlled randomised phase (Median 15 pills taken/month; 86% in active drug arm had TDF concentration consistent with PrEP use in the previous week)
  - **97% reduction** in HIV risk in open label extension

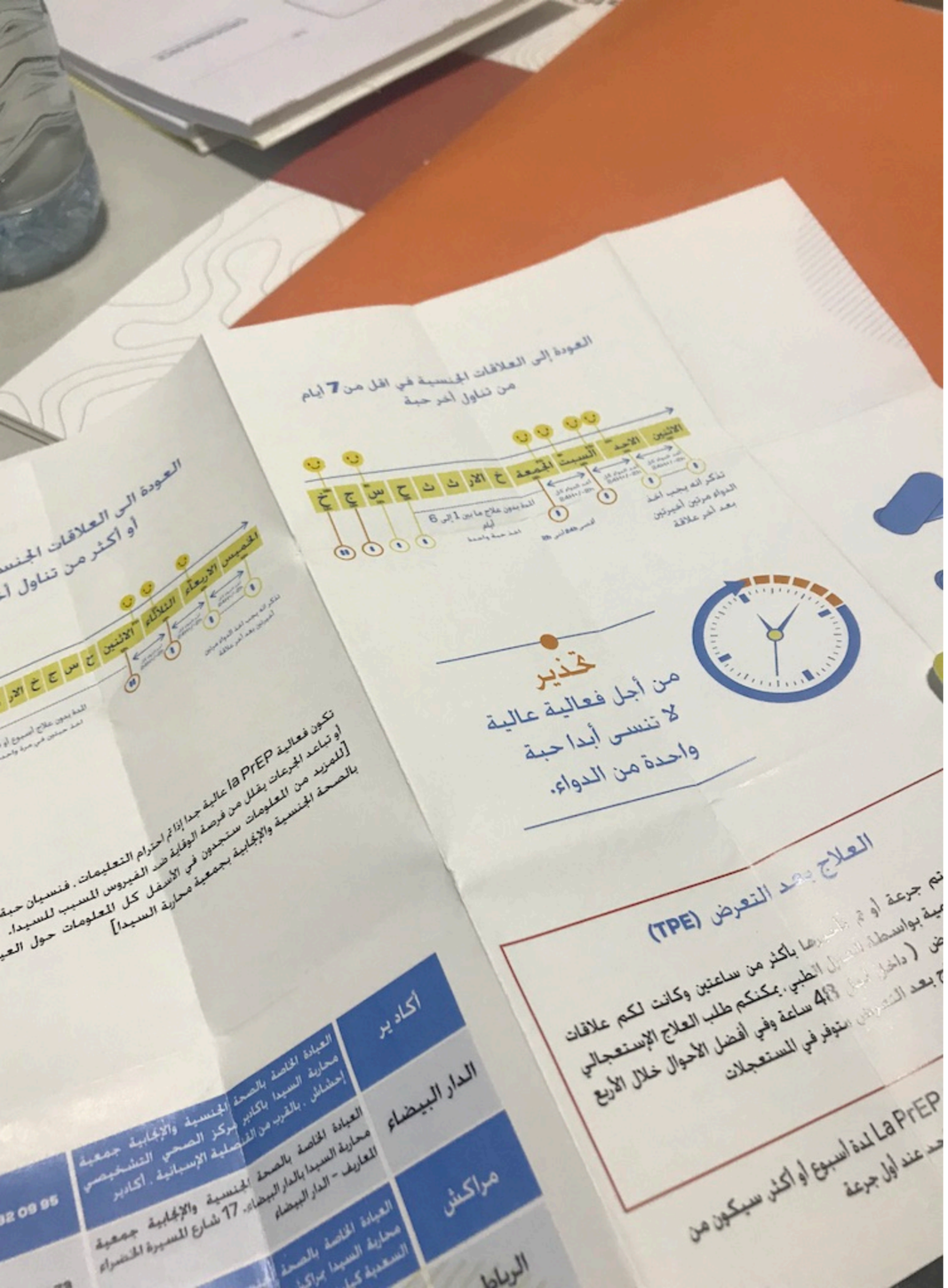
- Prevenir (2018) observational study in Paris (53% chose ED-PrEP) **(n ~ 3000):**
  - **0 infections** in ~500 person years of ED PrEP; 20% used PrEP and condoms (2018)

- No evidence among women, transgender persons, heterosexual men

JM Molina et al, New Engl J Med 2015; Lancet HIV 2017.

Guidelines/protocols recommending 211

- WHO
- National/professional society guidelines
  - United Kingdom (BHIVA)
  - Australian
  - Switzerland
  - European AIDS Clinical Society (EACS)
  - US (only city protocols)
    - San Francisco (Magnet clinic)
    - NYC
    - LA



Morocco PrEP programme (~300 people) is based on French guidance

- Question on intake (completed by doctor)
- Dosing dose recommended by doctor:
  - ‘Intermittent’
  - ‘Continuous’

ED-PrEP: acceptability and preference

% of MSM choosing event driven

- **Belgium:** 23.5% chose ED-PrEP (*Reyniers T 2018*)
- **Canada**: L'Actuel: 22% when offered as alternative (*Greenwald Z et al*, 2017)
- **China:** 58% interested in ED-PrEP trial (*Mao X et al*, 2017)
- **France:** 40% interested in ED-PrEP trial (*Lorent N et al*, 2012);
  53% in Prevenir study (*Molina J-M et al*, 2018);
  76% (*Noret M et al*, 2018)
- **The Netherlands**: 27% chose ED-PrEP (*Hoornemborg E et al*, 2019)
- **UK:** ~17% (Public Health England, PrEPster, IWantPrEPNow)
- **USA**: 74% in MSM who declined daily dosing (*Beymer MR at al*, 2018)

WHAT ARE THE POTENTIAL RISKS OF ED-PREP IN MEN WHO HAVE SEX WITH MEN?

Forgetting to take post-sex dose

211 fails

Resistance

Choosing 211 = gay

There are concerns that using ED-PrEP, and consistently taking the correct regimen, may be difficult for some people. Where ED-PrEP and daily PrEP are offered to men who have sex with men they can be supported to choose the option they prefer. However it is recognized that in some settings where clinics offer PrEP services to a range of populations including men who have sex with men (both those who identify as such and those do not), a single option of daily PrEP may be preferred. Further, daily dosing should be offered as an alternative that may be easier to use and is preferable when sex events are frequent and/or unplanned.

HIV drug resistance could emerge as a result of exposure of the HIV virus to antiretroviral drugs during suboptimal adherence to a PrEP regimen and consequent breakthrough infection. Resistance to FTC and/or TDF was infrequently reported in randomised controlled trials owing largely to the low incidence of HIV infection if PrEP is taken and the lack of drug exposure if adherence to PrEP is low *(10)*. Participants in the active arm of the Ipergay trial demonstrated high levels of adherence to PrEP, and no HIV infections occurred in people using ED-PrEP *(45)*.In the Prevenir study, two HIV infections occurred among ED-PrEP participants after they had discontinued PrEP; neither was drug resistant (*47*).

Conversely, HIV drug resistance was more commonly reported if oral TDF/FTC PrEP was inadvertently initiated during undiagnosed HIV infection *(10)*. As exposure to antiretroviral drugs in individuals with undiagnosed HIV represents the main risk for drug resistance acquisition associated with PrEP, it is imperative to take all reasonable steps to exclude HIV infections before PrEP initiation or reinitiation and to ensure consistent and frequent HIV testing while PrEP is administered.

HIV testing is recommended every three months both for people taking daily oral and for those taking ED-PrEP, usually coinciding with clients collecting their next prescription for PrEP drugs. Some clinicians have raised concerns that drug resistance risk may be higher with ED-PrEP because drug exposure is episodic and HIV testing may not occur before PrEP use. People taking ED-PrEP infrequently may theoretically become HIV infected in periods where they are off PrEP, with subsequent increased risk of resistance if ED-PrEP is taken without prior HIV testing ruling out HIV infection.

Monitoring ED-PrEP implementation and ensuring that follow-up monitoring every three months for HIV testing is an important component of PrEP interventions.

While it is informative for routine monitoring to disaggregate PrEP use by daily oral and ED-PrEP, a potential unintended consequence of monitoring ED-PrEP may be that it identifies men who have sex with men in recording and reporting systems since ED-PrEP is a dosing option only for men who have sex with men. Another is that undeclared men who have sex with men may have daily PrEP prescribed to avoid this identification but may decide on their own to use event-driven dosing. Monitoring may identify these users as apparently non-continuous if continuation is measured by number of pills taken. Furthermore, such users will not receive instructions for how to use ED-PrEP safely. Confidentiality and protection of health data are critical, and especially so in settings where men who have sex with men are marginalized and same-sex activity is criminalized. Establishing data systems with in-built protections, particularly for electronic records and reporting forms containing potentially identifying information, will be important both to ensure data security and to foster trust among PrEP users.

How to take event based PrEP

5,984 views • Oct 1, 2018

33

Dean Street (London, UK)

https://www.youtube.com/watch?v=KX_dutWnyYA

- Recommended for anal sex ONLY
- People who can predict your sex
- Make sure you do not miss dose
- hepB contraindicated
- Check your hepB status
- Daily and ED PrEP are just as effective
- Ensure there at least 2 doses
- Go read i-base leaflet

other products

European Medicines Agency (EMA) approval of the dapivirine ring for HIV prevention for women in high HIV burden settings

https://www.who.int/news-room/detail/24-07-2020-european-medicines-agency-(ema)-approval-of-the-dapivirine-ring-for-hiv-prevention-for-women-in-high-hiv-burden-settings

Products In Development

IPM Clinical Trials

Access

Dapivirine Ring

Fast facts

- Acts against: HIV-1
- Delivery method: Silicone matrix vaginal ring
- Active ingredient: Dapivirine, an antiretroviral drug
- Length of action: One month, with a three-month ring in development
- Status: Received positive opinion from European Medicines Agency, with country regulatory submissions planned; open-label studies underway among adolescents & young women, pregnant and breastfeeding women

Why is the dapivirine ring important?

Existing prevention methods have not done enough to stop the spread of HIV among women, who bear a disproportionate burden of the epidemic, particularly in sub-Saharan Africa. Pending regulatory approval, the monthly dapivirine ring would provide women with the first discreet, long-acting prevention option.

How does the dapivirine ring work?

The ring is made of a flexible silicone matrix polymer and contains the ARV dapivirine, an NNRTI, which is slowly released over the course of a

▼ Our Work
- ▼ Our Products
  - ▼ Dapivirine Ring
    - Three-month Dapivirine Ring
    - Dapivirine-Contraceptive Ring
    - DS003-Dapivirine Ring
    - Darunavir Ring
  - Our ARVs
  - Designing Products for Women
  - Preclinical Development
  - IPM Studies
  - Clinical Trials
  - Pathway to Microbicide Access
  - Glossary

https://www.ipmglobal.org/our-work/our-products/dapivirine-ring

The ring is effective (but not as effective as TDF/FTC)

- Two phase III clinical trials – MTN-020/ASPIRE and IPM 027/The Ring Study – showed that the monthly dapivirine vaginal ring was well tolerated and reduced HIV-1 incidence by approximately 30% compared to placebo.

- Two additional open label extension studies were conducted (HOPE and DREAM)

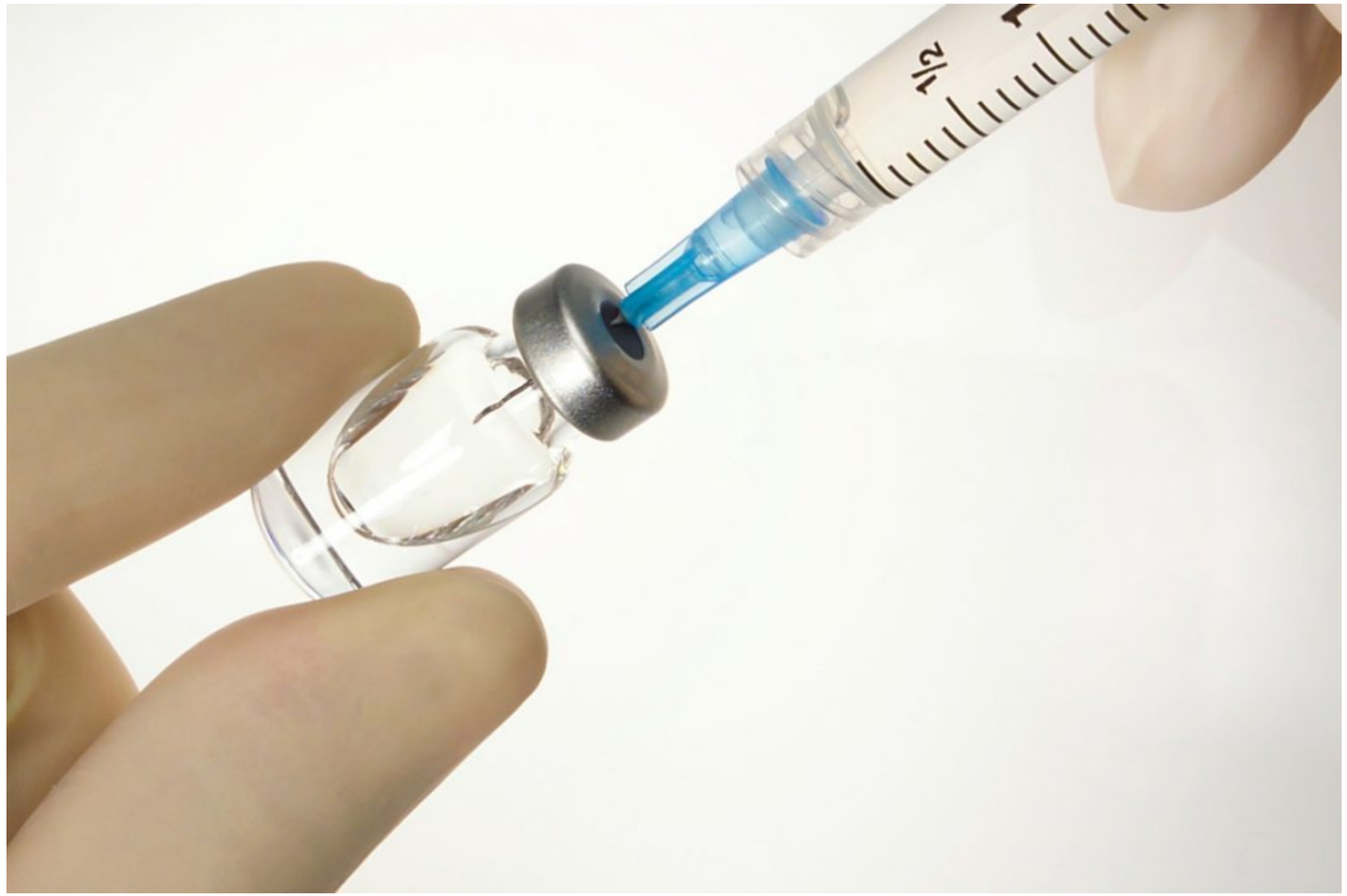
ASPIRE

THE RING STUDY
Developing HIV Prevention for Women

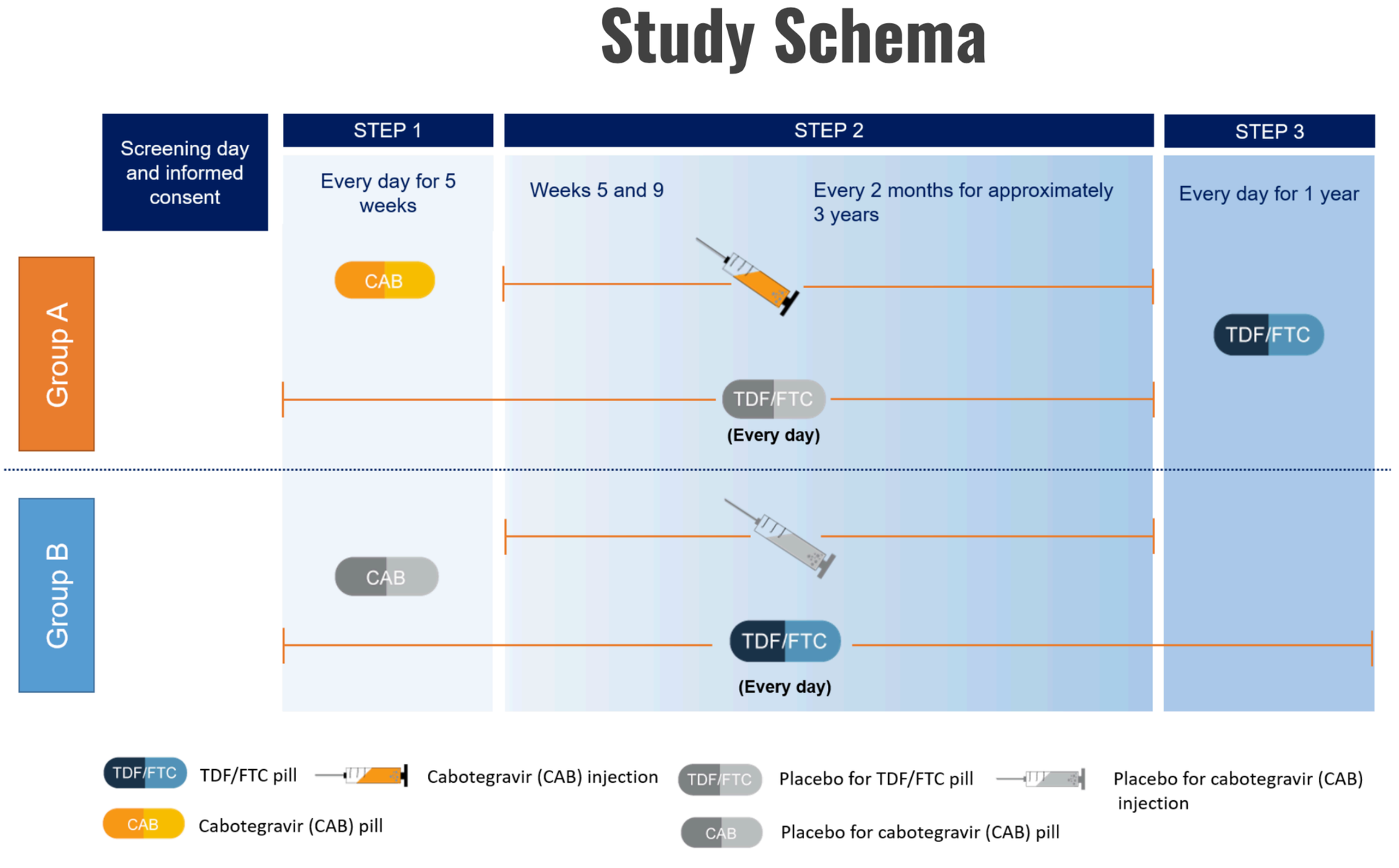
Baeten et al., Nel et al., NEJM 2016

Long acting injectable: cabotegravir

- HPTN 083
- HPTN 084



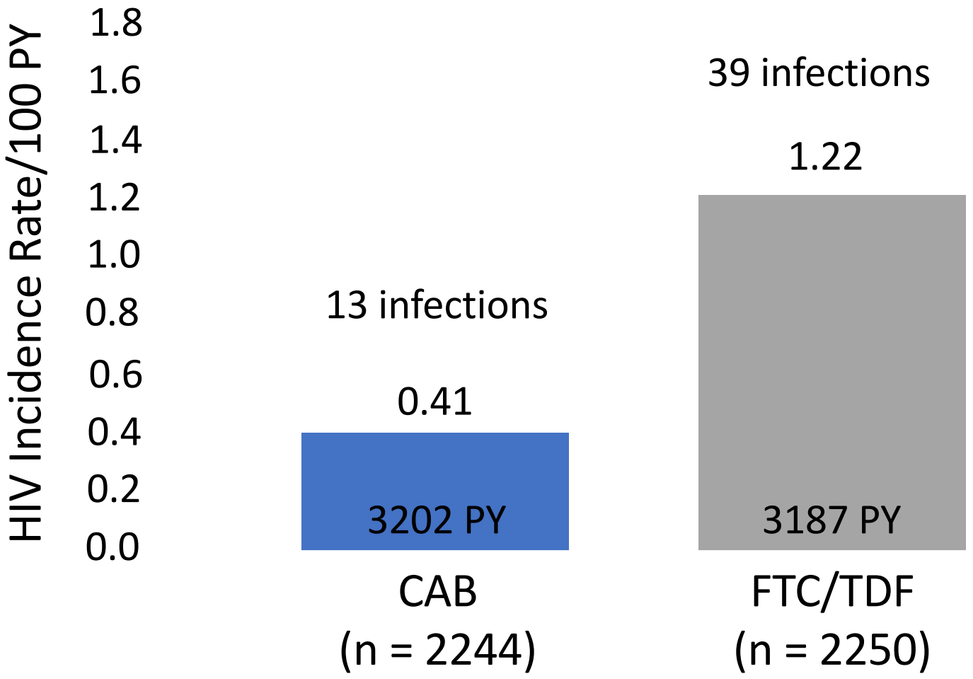
HPTN 083: International, randomized, double-blind phase IIb/III study



HPTN 083: HIV Incidence

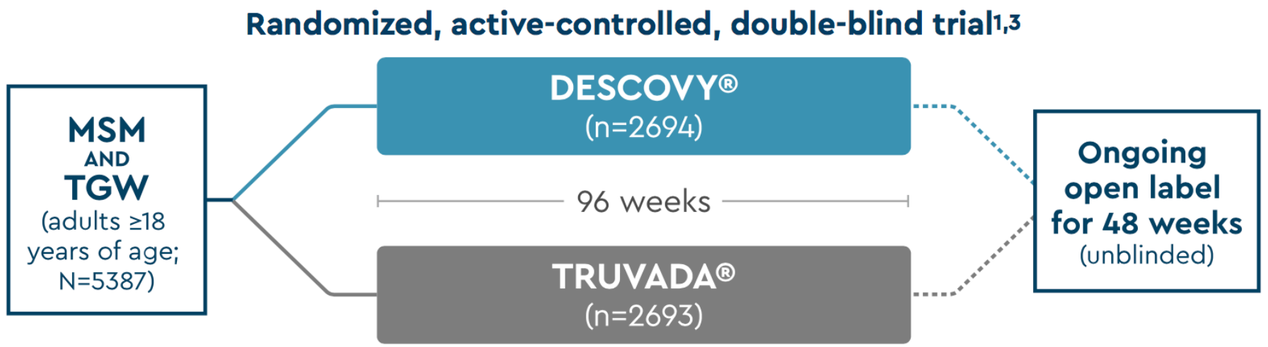
- Pooled incidence: 0.81 per 100 PY (95% CI: 0.61-1.07)
  - 52 HIV infections in 6389 PYFU

Median follow-up per participant: 1.4 yrs (IQR: 0.8-1.9).



Landovitz. AIDS 2020. Abstr OAXLB0101.

DISCOVER trial: TAF/FTC (Descovy) vs TDF/FTC (Truvada) in cis-MSM and transgender women

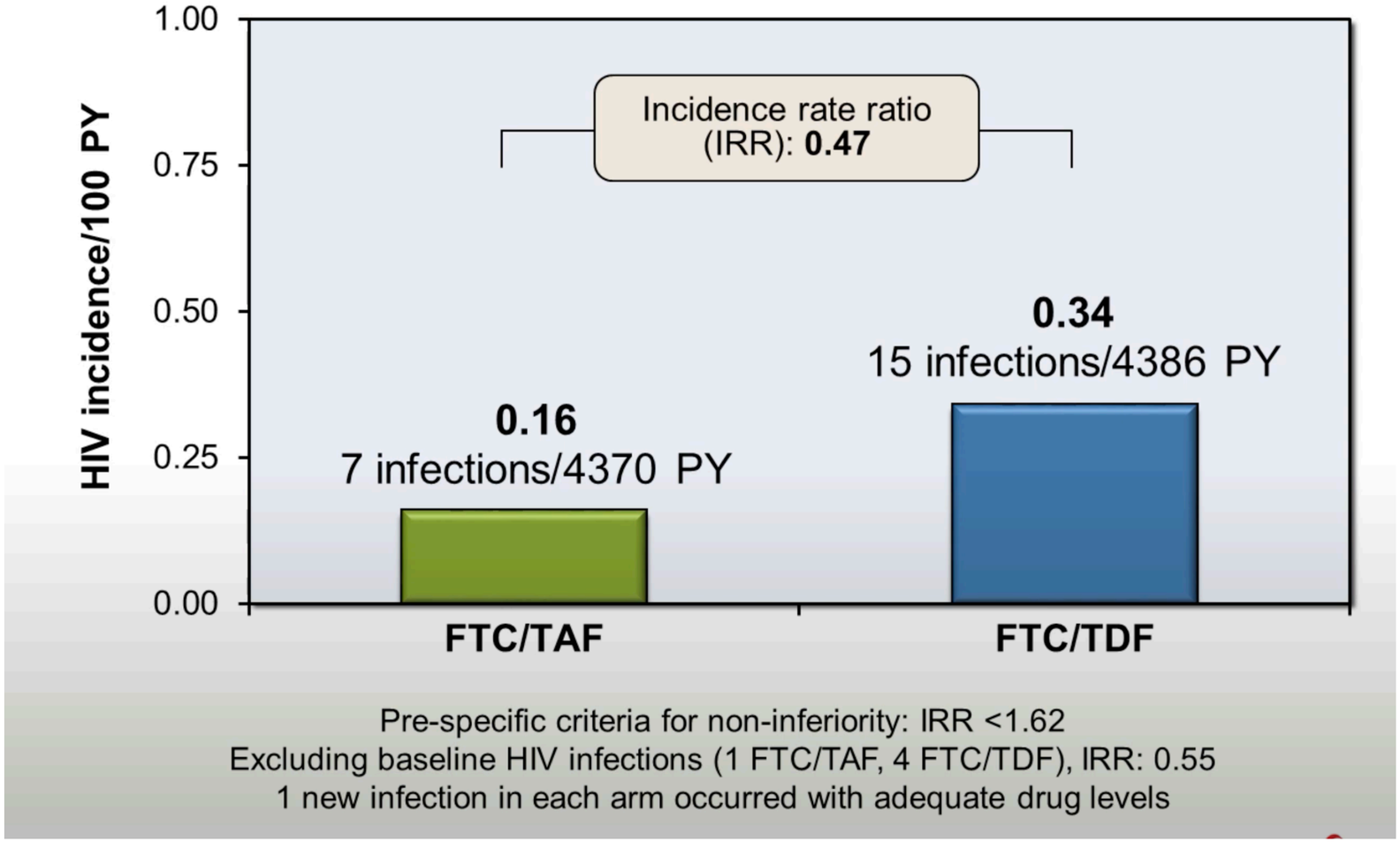


INDICATION View all

DESCOVY for HIV-1 pre-exposure prophylaxis (PrEP) is indicated in at-risk adults and adolescents (≥35 kg) to reduce the risk of sexually acquired HIV-1 infection, excluding individuals at risk from receptive vaginal sex. HIV-1–negative status must be confirmed immediately prior to initiation.

Limitation of Use: DESCOVY FOR PrEP® is not indicated in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated.

DISCOVER trial: TAF/FTC vs TDF/FTC (non-inferiority) in cis-MSM and transgender women



Tenofovir Alafenamide for HIV Preexposure Prophylaxis: What Can We DISCOVER About Its True Value?

Douglas S. Krakower, MD; Demetre C. Daskalakis, MD; Judith Feinberg, MD; and Julia L. Marcus, PhD

In early 2019, the U.S. government launched the Ending the HIV Epidemic initiative, which aims to reduce HIV incidence by 90% before 2030. Daily preexposure prophylaxis (PrEP) with a single pill containing tenofovir disoproxil fumarate with emtricitabine (TDF–FTC) virtually eliminates sexual HIV transmission, and scale-up of PrEP is a critical component of the federal initiative. Before TDF–FTC was used for PrEP, it was a cornerstone of HIV treatment, but it has been largely replaced by tenofovir alafenamide with emtricitabine (TAF–FTC), a newer regimen that was believed to be equally effective but safer. As we embark on a national effort to scale up PrEP, should we also abandon TDF–FTC in favor of TAF–FTC for HIV prevention?

Until recently, when people thought of PrEP, they thought of TDF–FTC's brand name in the United States, Truvada. However, in October 2019, the U.S. Food and Drug Administration approved TAF–FTC (Descovy) for PrEP. Gilead Sciences, which manufactures both Truvada and Descovy, has claimed that TAF–FTC is safer (1) and more effective (2) than TDF–FTC for PrEP. If TAF–FTC were indeed safer and more effective, there would be broad implications for patients, clinicians, and payers because hundreds of thousands of persons who use TDF–FTC PrEP would presumably switch to TAF–FTC, and those initiating PrEP—more than 1 million Americans at full scale—would use the newer formulation. This also has major financial implications for Gilead: Generic TDF–FTC will become available in 2020, whereas Gilead has exclusive rights to manufacture TAF–FTC until 2022 and is pursuing a patent extension until 2025. Thus, having TAF–FTC as the preferred PrEP option would extend Gilead's market dominance for years to come.

So, what does the evidence tell us about these 2 PrEP options?

Robust data show the efficacy of TDF–FTC PrEP for populations affected by HIV, including men who have sex with men (MSM), transgender women, persons who inject drugs, and heterosexuals whose partners are living with HIV. The data are so compelling that the U.S. Preventive Services Task Force issued a grade A recommendation for this regimen in 2019. In contrast, the only efficacy data for TAF–FTC are from a single randomized trial, DISCOVER, that showed that TAF–FTC was noninferior to TDF–FTC as once-daily PrEP (1). Of note, DISCOVER enrolled only MSM and a very small number of transgender women; thus, Food and Drug Administration approval for TAF–FTC as PrEP excluded those at risk from "receptive vaginal sex," and its efficacy remains unknown for other priority populations, including persons who inject drugs (3). In the future, no HIV prevention drug should be allowed to undergo Food and Drug Administration review without data addressing *all* key populations at risk for HIV.

Is TAF–FTC more effective than TDF–FTC for PrEP? Pharmacokinetic data suggest that TAF rapidly achieves higher and more sustained drug levels than TDF in the peripheral blood mononuclear cells targeted by HIV (2). However, TAF achieves lower concentrations in the genital and rectal mucosa (4), and there is no consensus on pharmacokinetic correlates of protection for PrEP. More important, TAF–FTC did not meet criteria for superior efficacy compared with TDF–FTC. Thus, although patients and clinicians can consider daily TAF–FTC and TDF–FTC to be equally efficacious for MSM and possibly transgender women, it would be a clinical leap of faith to use TAF–FTC instead of TDF–FTC in other populations.

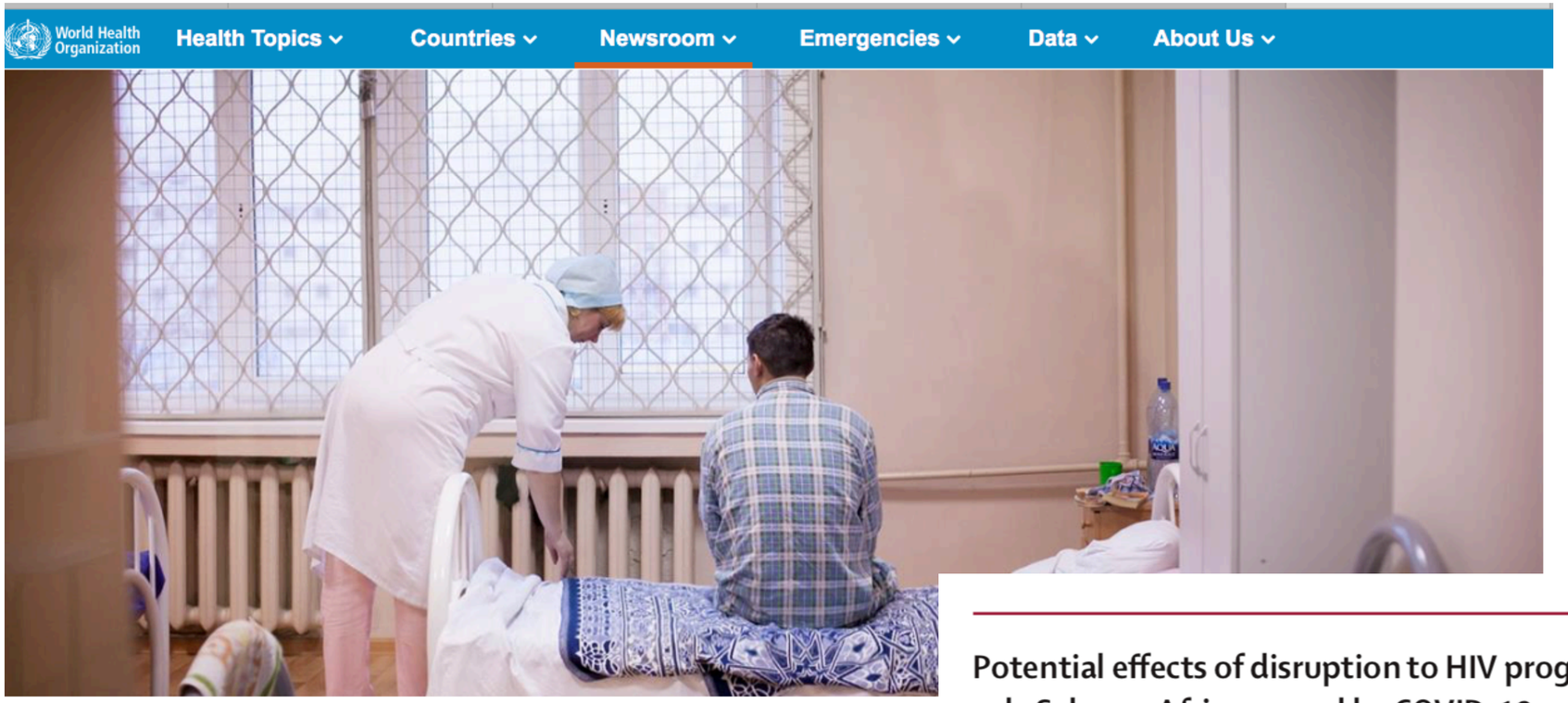
The faster achievement of drug levels by TAF could theoretically be favorable for event-driven PrEP (that is, short courses of pericoital PrEP), where HIV exposure occurs soon after pill ingestion. But event-driven PrEP with TDF–FTC is more than 90% effective for MSM—the only population in which event-driven PrEP has been studied—leaving little room for improvement. In the absence of efficacy data for event-driven TAF–FTC, and without recommendations for event-driven TDF–FTC PrEP from the Centers for Disease Control and Prevention, prescribing event-driven TAF–FTC would be far afield of current guidelines.

Is TAF–FTC safer than TDF–FTC for PrEP? When used as part of multidrug regimens for HIV treatment, TDF can cause renal or bone adverse events (5, 6), whereas TAF is associated with weight gain and changes in lipid parameters (7), although serious harms are rare. However, a decade's worth of research has demonstrated the excellent safety of TDF–FTC used as PrEP. A systematic review of TDF–FTC or TDF alone used as PrEP by thousands of trial participants found no differences in renal or bone harms compared with placebo or no treatment (8). It is also reassuring that more than 200 000 U.S. patients have been prescribed TDF–FTC PrEP and no serious toxicities have been reported.

DISCOVER found incremental differences in safety variables between the 2 drugs. Some favored TAF–FTC and others TDF–FTC (**Table**): TDF–FTC was associated with decreases in renal glomerular function biomarkers and bone mineral density, whereas TAF–FTC was linked to weight gain and dyslipidemia (4, 9). However, these statistically significant changes were not clinically relevant. Almost no participants in either group stopped using PrEP because of adverse events. The preponderance of evidence suggests that both PrEP formulations are as safe as other commonly used preventive medications, such as oral contraceptives and statins

This artic
Annals.o

How do you maintain something that you haven’t started implementing?



The cost of inaction: COVID-19-related service disruptions could cause hundreds of thousands of extra deaths from HIV

A 6-month interruption in ART supplies for 50% of people would be expected to lead to an approximately 1·63 times (range 1·39–1·87) increase in HIV-related deaths over 1 year.

In sub-Saharan Africa, this increase amounts to a **median of 296 000** (range 229 023–420 000) excess HIV deaths over this period.

This substantial number of excess deaths can be explained by the fact that CD4 lymphocyte cell count recovery, which takes years to achieve on ART, is rapidly lost after viral replication resumes in the absence of ART.

Potential effects of disruption to HIV programmes in sub-Saharan Africa caused by COVID-19: results from multiple mathematical models

Britta L Jewell, Edinah Mudimu*, John Stover*, Debra ten Brink*, Andrew N Phillips*, Jennifer A Smith, Rowan Martin-Hughes, Yu Teng, Robert Glaubius, Severin Guy Mahiane, Loveleen Bansi-Matharu, Isaac Taramusi, Newton Chagoma, Michelle Morrison, Meg Doherty, Kimberly Marsh, Anna Bershteyn, Timothy B Hallett, Sherrie L Kelly, for the HIV Modelling Consortium*

Summary

Background The COVID-19 pandemic could lead to disruptions to provision of HIV services for people living with HIV and those at risk of acquiring HIV in sub-Saharan Africa, where UNAIDS estimated that more than two-thirds of the approximately 38 million people living with HIV resided in 2018. We aimed to predict the potential effects of such disruptions on HIV-related deaths and new infections in sub-Saharan Africa.

Methods In this modelling study, we used five well described models of HIV epidemics (Goals, Optima HIV, HIV Synthesis, an Imperial College London model, and Epidemiological MODeling software [EMOD]) to estimate the effect of various potential disruptions to HIV prevention, testing, and treatment services on HIV-related deaths and new infections in sub-Saharan Africa lasting 6 months over 1 year from April 1, 2020. We considered scenarios in which disruptions affected 20%, 50%, and 100% of the population.

Findings A 6-month interruption of supply of antiretroviral therapy (ART) drugs across 50% of the population of people living with HIV who are on treatment would be expected to lead to a 1·63 times (median across models; range 1·39–1·87)

Lancet HIV 2020; 7: e629–40
Published Online August 6, 2020 https://doi.org/10.1016/S2352-3018(20)30211-3
See Comment page e596

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https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(20)30211-3/fulltext

COVID-19: the major disruptor in HIV services

- As part of the COVID-19 response, many countries are adapting their HIV programmess to protect recipients of care and health care workers
  - Decreasing contact with health facilities
  - Expanding multi-month dispensing (MMD) of ART and other medications
  - Telemedicine
  - Courier services for delivery of PrEP

BRAZ J INFECT DIS 2020;24(4):360–364

The Brazilian Journal of
INFECTIOUS DISEASES

www.elsevier.com/locate/bjid

Brief communication

Telemedicine as a tool for PrEP delivery during COVID-19 pandemic in a large HIV prevention service in Rio de Janeiro-Brazil

Brenda Hoagland [a,*], *Thiago S. Torres* [a], *Daniel R.B. Bezerra* [a], *Cristina Pimenta* [b], *Valdilea G. Veloso* [a], *Beatriz Grinsztejn* [a]

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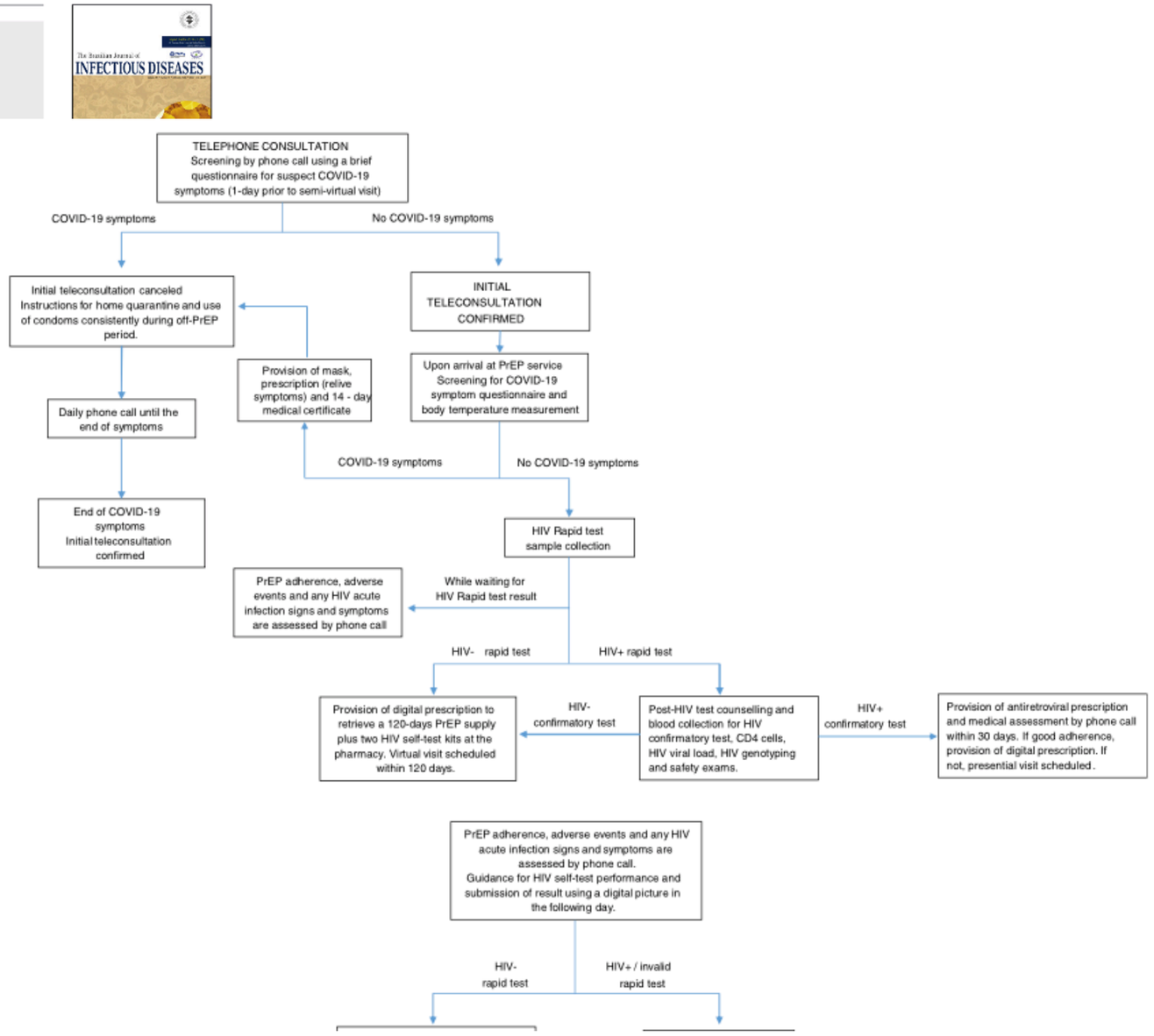
[b] *Brazilian Ministry of Health, Brasilia, DF, Brazil*

ARTICLE INFO

Article history:

ABSTRACT

COVID-19 public health responses such as social distanc



- https://reader.elsevier.com/reader/sd/pii/S1413867020300659?token=AD40A8E4A8F455DC9CBA0A01015BC0B202EAAD74B45942A678A7331E6A56AFA717C958C6B5CB2AD5E458741A07FCAF4E

PrEP ‘effective use’ concept introduced to MSM clients in Thailand

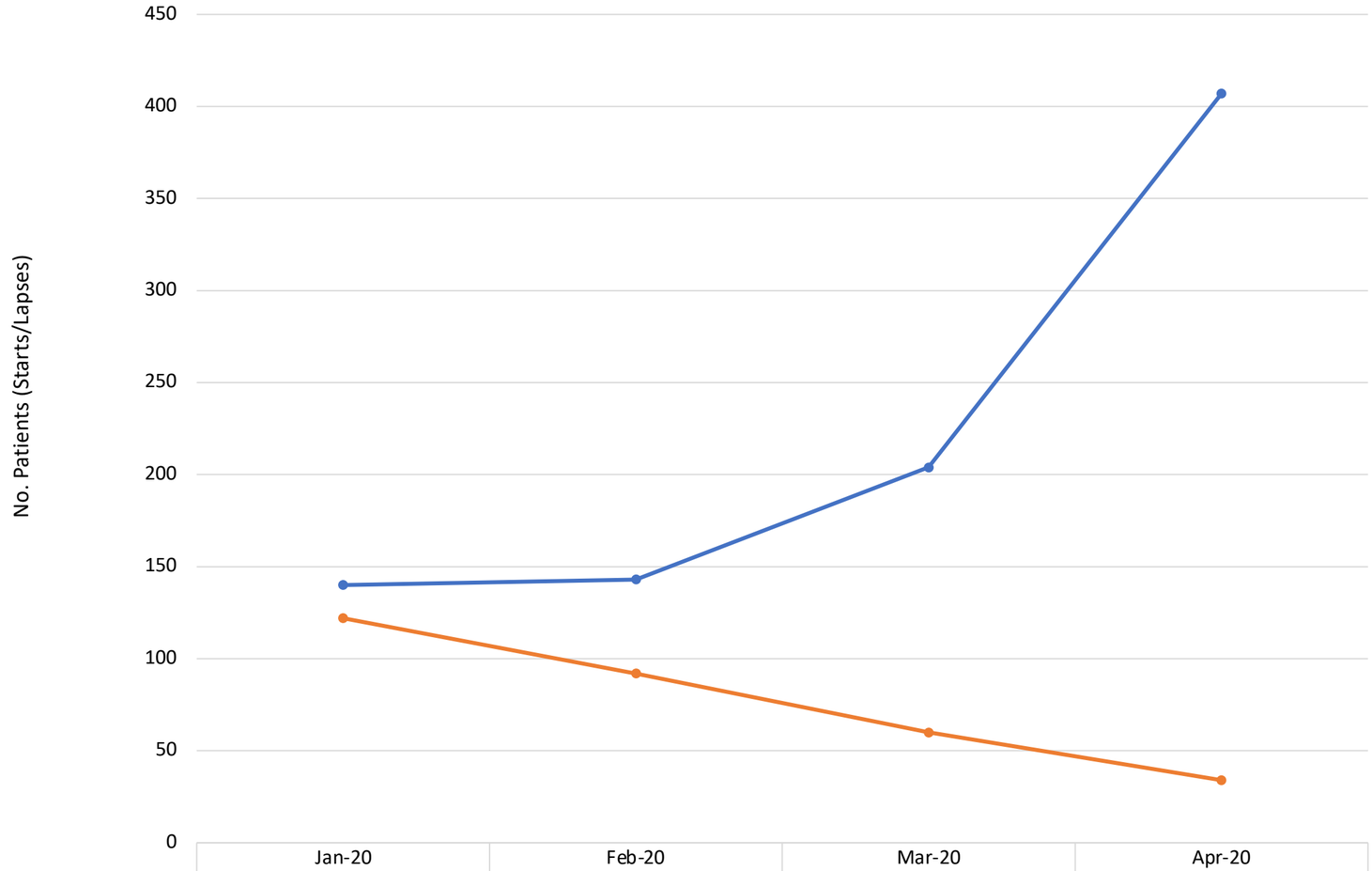
- Issues with raw materials and generic drugs shipment and custom clearance causing unstable supply chain
- Choose to stop/re-start and tailor daily/event-driven PrEP use, according to risks

PrEP refill lapses increased by 191% in community sexual health center in Boston, USA

	Jan-20	Feb-20	Mar-20	Apr-20
PrEP Lapses	140	143	204	407
New Starts	122	92	60	34

Krakower et al. OACLB0104

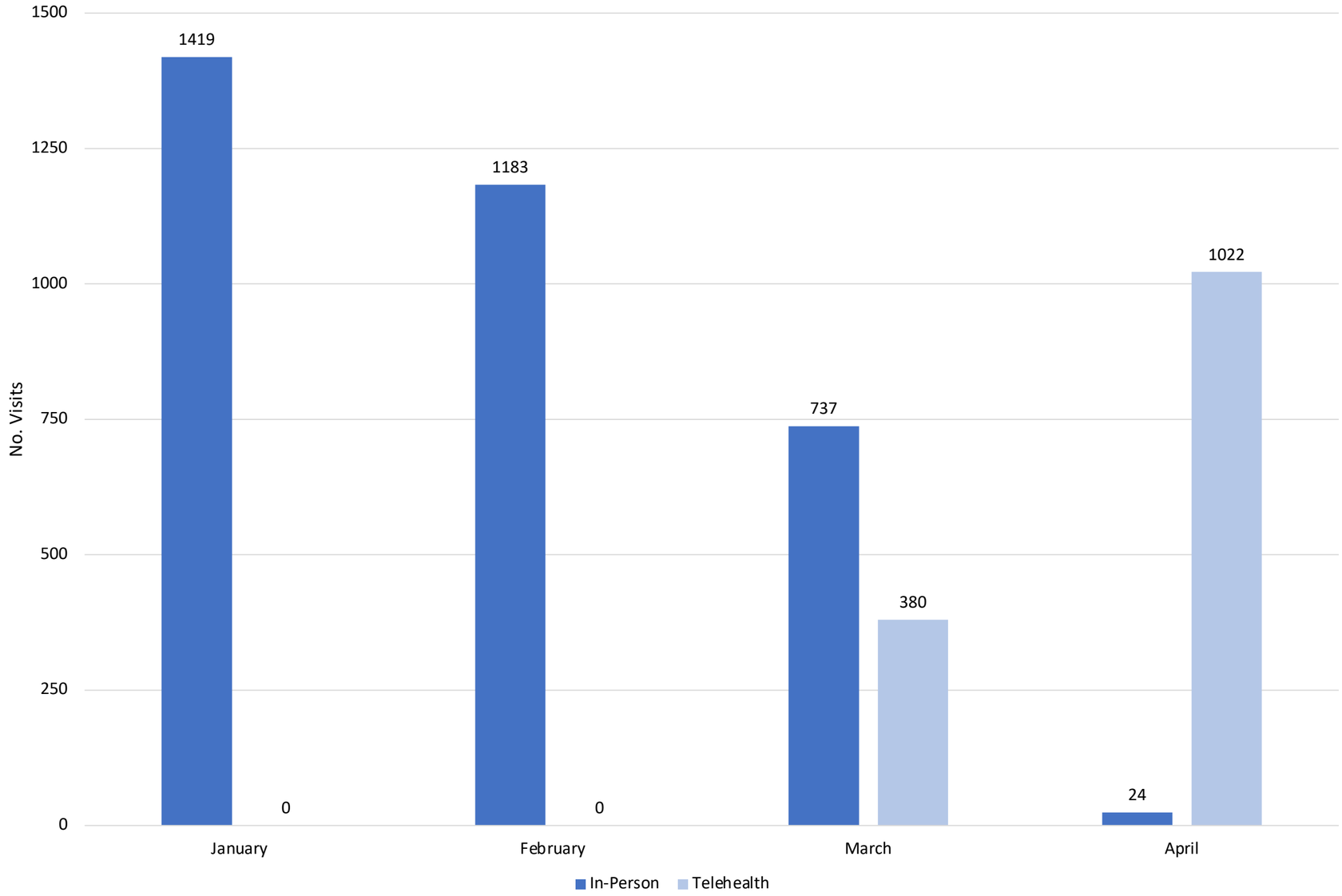
New PrEP starts decreased by 72.1%



	Jan-20	Feb-20	Mar-20	Apr-20
PrEP Lapses	140	143	204	407
New Starts	122	92	60	34
Start of Month Cohort Size	3197	3179	3128	2984

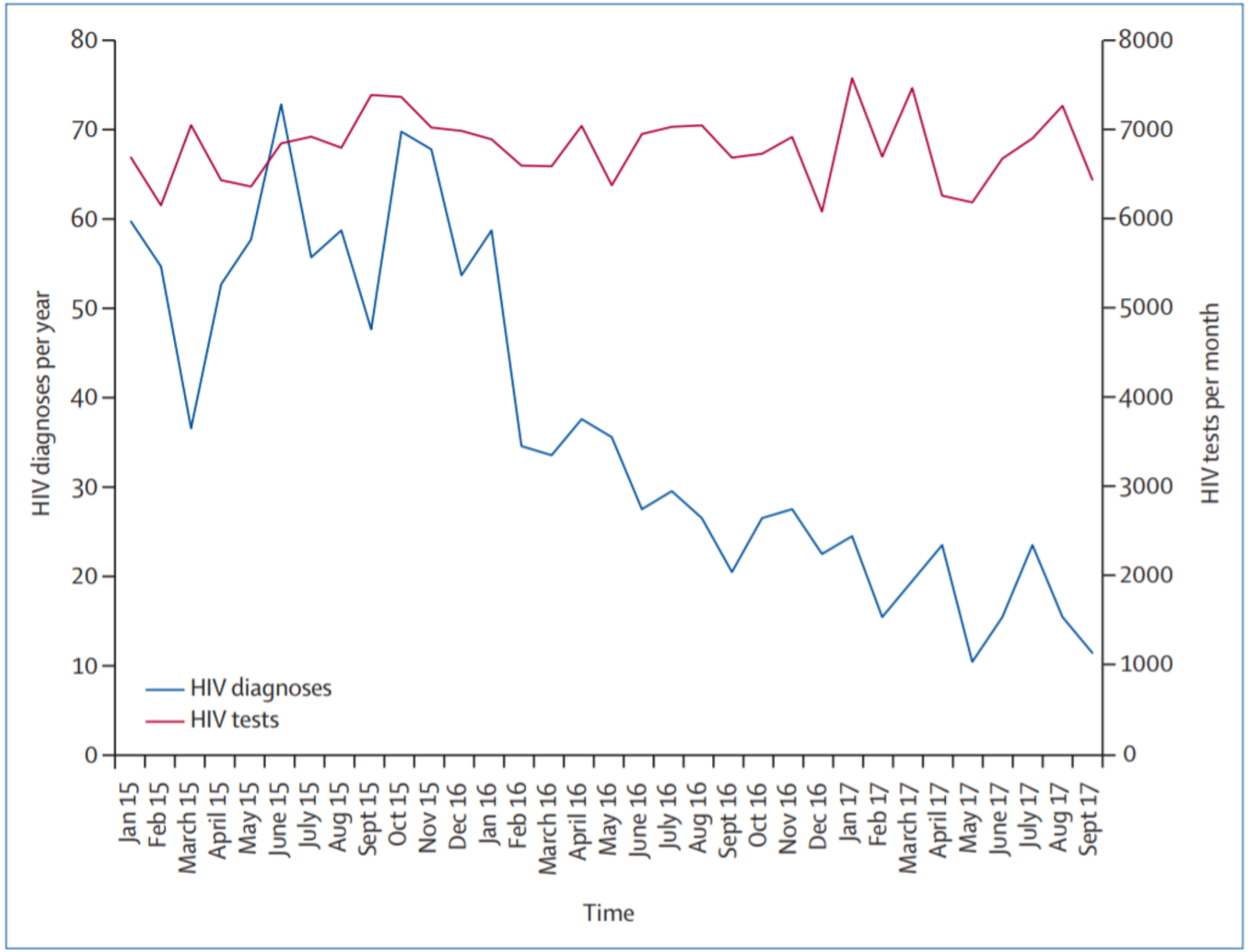
Krakower et al. OACLB0104

A major shift from in-person visits to telehealth occurred



Krakower et al. OACLB0104

Impact of increasing PrEP coverage on new HIV diagnoses in London (sexual health clinic, Dean St.): could you demonstrate this in one of your HIV/STD clinics as part of a pilot?



Source: Nwokolo et al, 2107 (Lancet HIV) https://www.thelancet.com/pdfs/journals/lanhiv/PIIS2352-3018(17)30181-9.pdf

How did Dean Street pivot during surge?

- Services at clinic remained open but staff were also redeployed to help with the COVID effort in main hospital

- Other STI clinics that are also part of Chelsea & Westminster hospital (John Hunter clinic, 10 Hammersmith Broadway) closed.

- For STI management:
  - Created telephone triage and directed as many callers as possible to defer attendance (e.g. chronic problems like BV, warts) and to test for STIs by postal testing kits (Sexual Health London).
  - Where possible, treatments were sent by post or even prescriptions were dispatched to patient's homes to collect from local pharmacies.

- PrEP management was similar to STI management
  - Where possible, clinic tried to NOT interrupt access to PrEP
  - Encouraged PrEP users to do postal STI testing (including HIV tests)
  - If renal function was needed, they would see them face-to-face if necessary
  - posted out PrEP if required.

Source: Communication with Gary Whitlock

Vietnam HIV self-testing

Step 1 — Online reach & risk assessment
- View HIVST advertisement
- Complete online risk assessment
- Self-identify HIV testing needs

Step 2 — Online test order
- Select/fill out online HIVST delivery order (mail, grab, self-pick up)

Step 3 — HIVST kit delivery
- HIVST kits delivered to clients within 48h
- Client confirms receipt through Zalo/SMS

Step 4 — Follow-up HIVST
- Perform HIVST, using instructions-for-use and/or video
- Provide feedback to distributors via telephone, Zalo, SMS within 7 days
- If no feedback, distributor calls the client.

‘Grab’ delivery

- Slide courtesy of: Kimberly Green (PATH)

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Performance of the Cepheid CT/NG Xpert Rapid PCR Test for Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

Charlotte A. Gaydos,[a] Barbara Van Der Pol,[b,c] Mary Jett-Goheen,[a] Mathilda Barnes,[a] Nicole Quinn,[a] Carey Clark,[d] Grace E. Daniel,[c] Paula B. Dixon,[d] Edward W. Hook III,[d] The CT/NG Study Group

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Tests for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, which can provide results rapidly to guide therapeutic decision-making, offer patient care advantages over laboratory-based tests that require several days to provide results. We compared results from the Cepheid GeneXpert CT/NG (Xpert) assay to results from two currently approved nucleic acid amplification assays in 1,722 female and 1,387 male volunteers. Results for chlamydia in females demonstrated sensitivities for endocervical, vaginal, and urine samples of 97.4%, 98.7%, and 97.6%, respectively, and for urine samples from males, a sensitivity of 97.5%, with all specificity estimates being ≥99.4%. Results for gonorrhea in females demonstrated sensitivities for endocervical, vaginal, and urine samples of 100.0%, 100.0%, and 95.6%, respectively, and for urine samples from males, a sensitivity of 98.0%, with all estimates of specificity being ≥99.8%. These results indicate that this short-turnaround-time test can be used to accurately test patients and to possibly do so at the site of care, thus potentially improving chlamydia and gonorrhea control efforts.

Chlamydia trachomatis and *Neisseria gonorrhoeae* are the agents of the two most prevalent bacterial sexually transmitted infections (STIs) reported to the Centers for Disease Control and Prevention (CDC), accounting for >1.6 million reported infections in the United States in 2010 (1). The CDC estimates that STIs cost the health care system $1.5 billion annually. Since these infections, especially chlamydia, are most often asymptomatic, the CDC recommends yearly screening for chlamydia in all sexually active women aged 16 to 25 years. Further, since coinfections are common, most diagnostic test platforms assay for both organisms. Nucleic acid amplification tests (NAATs) are now recommended by the CDC (2) as the tests of choice; however, current NAATs are classified as being of high or moderate complexity and might take 1 to 2 days for results to become available. New assays and new platforms that provide results at the time of patient visits are urgently needed, since many patients do not return for their results when laboratory-based tests that require several days for their results are performed (3, 4).

The Cepheid GeneXpert CT/NG (Xpert) assay is a rapid (<2 h to results) NAAT assay that can be performed in on-site laboratories. The assay detects the DNA of *C. trachomatis* and *N. gonorrhoeae* from endocervical, vaginal, and urine specimens of females, as well as from urine specimens of males, from both

Combo 2 assay (AC2) (Tigris platform; Gen-Probe, San Diego, CA) (6, 7, 8, 9) and the ProbeTec ET *C. trachomatis* and *N. gonorrhoeae* amplified DNA assays (BDPT) (Viper platform; Becton, Dickinson, Sparks, MD) (10, 11). Testing was performed according to the assay package inserts of each manufacturer. All sites obtained institutional review board approval for the trial and conducted the study in accordance with the approved protocol consistent with the principles of good clinical and laboratory practices.

Patient population. The sample size was calculated using the following statistical plan: sensitivity (both genders, all matrix) required ≥95%, and specificity (both genders, all matrix) required ≥98%. The required sample size calculations assumed that subjects would be enrolled from sites with an approximate prevalence range of 5% to 10% for *C. trachomatis* and 3% to 7% for *N. gonorrhoeae*. For each site, male prevalence rates were assumed to be 2% higher than for females.

Specimens were collected from consenting sexually active symptomatic and asymptomatic males and females attending obstetrics and gynecology (OB-GYN), sexually transmitted disease (STD), teen, public health, or family planning clinics. Specimen types included urine from males and females, as well as endocervical swabs and patient-collected vaginal swabs from women (collected from patients in a clinical setting). The urine from each patient was collected as first-catch urine, which was then divided into the three parts for use with the 3 different transport media, according to directions of each manufacturer.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3716060/pdf/zjm1666.pdf

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Fast and Accurate Diagnosis of Chlamydia and Gonorrhea

Ordering Info

https://www.youtube.com/watch?v=EikIA5q52q4

Key points

- 211 should be included in national guidelines for PrEP
- More products in the pipeline, and more options for individuals to keep themselves HIV negative
- Diversify PrEP models
  - Longer PrEP refills?
  - PrEP closer to home?
  - Cadre of service providers (beyond clinicians – peers, community providers)

“We need to think of community dimension”, Dr Mike Ryan